



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 874

[Docket No. FDA-2015-N-2525]

Medical Devices; Ear, Nose, and Throat Devices; Classification of the External Upper Esophageal Sphincter Compression Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the external upper esophageal sphincter (UES) compression device into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the external UES compression device's classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The classification was applicable on March 6, 2015.

FOR FURTHER INFORMATION CONTACT: Sunny Park, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2432, Silver Spring, MD, 20993-0002, 301-796-7059, sunny.park@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i), to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1), the person requests a classification under section 513(f)(2) of the FD&C Act. Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and

requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of “low-moderate risk” or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device. On November 22, 2013, Somna Therapeutics, LLC, submitted a request for classification of the REZA BAND UES Assist Device under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on March 6, 2015, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 874.5900.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for an external UES compression device will need to comply with the special controls named in this final order. The device is assigned the generic name external UES compression device, and it is identified as a prescription device used to apply external pressure on the cricoid cartilage for the purpose of reducing the symptoms of laryngopharyngeal reflux disease.

FDA has identified the following risks to health associated specifically with this type of device, as well as the mitigation measures required to mitigate these risks, in table 1.

Table 1.--External UES Compression Device Risks and Mitigation Measures

Identified Risk	Mitigation Method
Adverse tissue reaction	Biocompatibility assessment
Risk of overcompression	Clinical study Labeling Technical specifications
Device misuse/incorrect fitting/malfunctions	Technical specifications Clinical study Labeling Performance testing (mechanical integrity and shelf life testing)

FDA believes that the following special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness:

1. The patient contacting components must be demonstrated to be biocompatible.
2. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be demonstrated:
 - a. Mechanical integrity testing (e.g., tensile strength testing, fatigue testing) and
 - b. shelf life testing
3. The technical specifications must include pressure measurement accuracy to characterize device performance.

4. Clinical performance testing must document any adverse events observed during clinical use, and demonstrate that the device performs as intended under anticipated conditions of use.
5. Labeling must include the following:
 - a. Appropriate warnings and precautions.
 - b. A detailed summary of the clinical testing pertinent to use of the device including a detailed summary of the device-related complications or adverse events.
 - c. Detailed instructions on how to fit the device to the patient.
 - d. Instructions for reprocessing of any reusable components.
6. Patient labeling must be provided and must include:
 - a. Relevant warnings, precautions, and adverse effects/complications.
 - b. Information on how to correctly wear the device.
 - c. The potential risks and benefits associated with the use of the device.
 - d. Alternative treatments.
 - e. Reprocessing instructions.

The external UES compression device is a prescription device restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device; see 21 CFR 801.109 (Prescription devices).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k), if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to

market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the external UES compression device they intend to market.

II. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910-0120, and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910-0485.

IV. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at <http://www.regulations.gov>.

1. DEN130046: De Novo Request per 513(f)(2) from Somna Therapeutics, LLC, dated November 11, 2013.

List of Subjects in 21 CFR Part 874

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 874 is amended as follows:

PART 874--EAR, NOSE, AND THROAT DEVICES

1. The authority citation for 21 CFR part 874 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Add § 874.5900 to subpart F to read as follows:

§ 874.5900 External upper esophageal sphincter compression device.

(a) Identification. An external upper esophageal sphincter compression device is a prescription device used to apply external pressure on the cricoid cartilage for the purpose of reducing the symptoms of laryngopharyngeal reflux disease.

(b) Classification. Class II (special controls). The special controls for this device are:

(1) The patient contacting components must be demonstrated to be biocompatible.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be demonstrated:

(i) Mechanical integrity testing (e.g., tensile strength testing, fatigue testing) and

(ii) Shelf life testing.

(3) The technical specifications must include pressure measurement accuracy to characterize device performance.

(4) Clinical performance testing must document any adverse events observed during clinical use, and demonstrate that the device performs as intended under anticipated conditions of use.

(5) Labeling must include the following:

- (i) Appropriate warnings and precautions,
 - (ii) A detailed summary of the clinical testing pertinent to use of the device including a detailed summary of the device-related complications or adverse events,
 - (iii) Detailed instructions on how to fit the device to the patient, and
 - (iv) Instructions for reprocessing of any reusable components.
- (6) Patient labeling must be provided and must include:
- (i) Relevant warnings, precautions, and adverse effects/complications,
 - (ii) Information on how to correctly wear the device,
 - (iii) The potential risks and benefits associated with the use of the device,
 - (iv) Alternative treatments, and
 - (v) Reprocessing instructions.

Dated: July 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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